UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PETER G. ANGELOS, Plaintiff, -against- TOKAI PHARMACEUTICALS, INC., JODIE POPE MORRISON, LEE H. KALOWSKI, SETH L. HARRISON, TIMOTHY J. BABERICH, DAVID A. KESSLER, JOSEPH A. YANCHIK, III, BMO CAPITAL MARKETS CORP., STIFEL, NICOLAUS & COMPANY, INCORPORATED, WILLIAM BLAIR & COMPANY, L.L.C., and JANNEY MONTGOMERY SCOTT LLC, Defendants.	Case No. ECF Case ECF Case: **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff, PETER G. ANGELOS, by and through his undersigned attorneys, as and for his Complaint against Defendants alleges as follows:

INTRODUCTION AND SUMMARY

1. This action concerns a developmental stage pharmaceutical company, its management, and its securities underwriters who falsely stated that the company had a promising drug candidate for the treatment of prostate cancer in patients with a specific genetic make-up. Receiving approval of the Food and Drug Administration ("FDA") and bringing this drug candidate to market was critical to the Company's viability. The Company and its investment bankers "took the company public" and raised over $100 million from investors based upon false statements concerning the candidate drug's past test results and the design of future tests to get FDA approval. Once a public company, further unlawful statements were issued to the public about the unapproved drug, one that could have been worth billions in revenue—if approved. As it turns out, the Phase 2 trials for the

drug were little more than cherry-picked data that was irrevelant, and the Phase 3 trials were discontinued early. Upon announcement that the Phase 3 trials were discontinued, the company's shares lost most of their value, and the Company was forced to reduce its work force.

2. Subsequently, it was revealed that the Phase 3 trials were discontinued *for lack of test subjects.* The company's disclosures were revealed to be false and misleading in several respects. The public now knows that at the time of the initial public offering, the drug candidate could not have been approved by the FDA due to faulty design of the trials. Because such approval was critical to the company's ongoing operations, the company, its management and investment bankers must have known that fact. Furthermore, when the Phase 3 trials were underway, not enough subjects could be recruited for a viable clinical trial. Again, this was a critical fact that had to have been known to the company.

3. Tokai Pharmaceuticals, Inc. ("Tokai" or the "Company") was a Massachusetts biopharmaceutical company focused on the development of a drug for prostate cancer. The Company's lead drug candidate was galeterone, a proposed product that, at all relevant times, was in various clinical trials for the treatment of patients with metastatic castration-resistant prostate cancer ("CRPC" or "mCRPC") with a specific genetic trait called "AR-V7."

4. This action is brought on behalf of Peter G. Angelos ("Plaintiff"): (a) under the Securities Act of 1933 (the "Securities Act"), with respect to Plaintiff's purchases of Tokai common stock traceable to Tokai's stock offering on September 17, 2014 (the "IPO"); and (b) under the Securities Exchange Act of 1934 (the "Exchange Act"), also with respect to Plaintiff's purchases of Tokai common stock on the open market.

5. Tokai's IPO was made pursuant to a false Registration Statement and Prospectus (the "Registration Statement"), through which the Company raised $105.3 million. Because this was Tokai's first and only IPO, all shares purchased by Plaintiff are traceable to the IPO. Tokai's Registration Statement filed with the U.S. Securities and Exchange Commission ("SEC") in furtherance of the IPO and Tokai's statements and public filings thereafter failed to disclose that the Company had not obtained meaningful data from its Phase 2 clinical data that would permit it to design a Phase 3 clinical trial that (i) could demonstrate sufficient efficacy, (ii) could be approved by the FDA; and (iii) were not significantly flawed; therefore, it was virtually certain that galeterone would not be approved by the FDA.

6. On July 26, 2016, Tokai disclosed that it had discontinued the Phase 3 trial of galeterone, based upon the recommendation made by the trial's independent Data Monitoring Committee (the "DMC"), which determined that the Phase 3 trial "will likely not succeed." This disclosure caused the price of Tokai stock to plummet.

7. On August 22, 2016, in a Form 8-K filed with the SEC, Tokai stated that it has determined to discontinue enrollment in its Phase 3 clinical trial of galeterone and not to proceed with its planned study of the drug.

8. Facts have finally emerged about the failure of the Phase 3 clinical trial of galerterone. The reason for the failure is simple and must have been known to Tokai and its management before July 26, 2016 – lack of test subjects. A summary of the trial is set forth on ClinicalTrials.gov, which is a service provided by the U.S. National Institutes of Health ("NIH"). The NIH data shows that Tokai anticipated 148 test subjects from the beginning of the study on or about May 7, 2015 to July 7, 2015, but stopped recruiting subjects on August

22, 2016. The reason for the stoppage did not become public until June 7, 2017 when at the annual meeting of the American Society of Clinical Oncology it was disclosed that the study had only 38 test subjects when the study was halted. Of those, 35 subjects "screen failed" and four were "discontinued at study halt." Significantly, the Company mislead investors into thinking there were 148 viable test subjects, when in fact, there were only four.

JURISDICTION AND VENUE

9. The claims asserted herein arise under Sections 11, 12(a)(2) and 15 of the Securities Act of 1933, 15 U.S.C. §§ 77k, 771(a)(2) and 770 and under Sections l0(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b) and 78t(a) and Rule l0b-5 promulgated thereunder. Jurisdiction is conferred by Section 22 of the Securities Act and Section 27 of the Exchange Act.

10. Venue is proper in the District, where Tokai had its principal place of business at 255 State Street, Boston, MA; where the Defendants conduct business or reside; and where the materially false and misleading Registration Statement and other documents complained of herein were prepared and disseminated.

THE PARTIES

11. Plaintiff, a resident of Maryland, purchased Tokai common stock pursuant and/or traceable to the IPO and was damaged thereby. Attached as Exhibit A is a summary of Plaintiff's purchases, sales, and losses in connection with Tokai common stock.

12. Defendant Tokai is a biopharmaceutical company whose shares traded on the NASDAQ Global Market under the symbol "TKAI." Tokai is a Delaware corporation. On or about May 11, 2017, after a corporate combination, the name of the surviving corporation was changed to Novus Therapeutics, Inc. The Company's common stock remains listed on

The NASDAQ Stock Market, under the new name as of May 11, 2017. The trading symbol also changed on that date from "TKAI" to "NVUS."

13. Defendant Jodie P. Morrison ("Morrison") is and at all relevant times was the Company's President and Chief Executive Officer and signed the Registration Statement. Between June 25, 2015 and July 29, 2015, Morrison sold roughly 28,564 shares of Tokai stock, for approximately $393,000.

14. Defendant Lee H. Kalowski ("Kalowski") was Tokai's Chief Financial Officer from September 2014 until his resignation on August 31, 2016. He signed the Registration Statement.

15. Defendant Seth L. Harrison ("Harrison") is and at all relevant times was Tokai's Chairman. He signed the Registration Statement.

16. Defendant Timothy J. Barberich ("Barberich") is and at all relevant times was a Company director. He signed the Registration Statement.

17. Defendant David A. Kessler ("Kessler") 1s and at all relevant times was a Company director. He signed the Registration Statement.

18. Defendant Joseph A. Yanchik, III ("Yanchik") is and at all relevant times was a Company director. He signed the Registration Statement.

19. Defendant BMO Capital Markets Corp. ("BMO") is a financial services company with principal executive office located at 3 Times Square, New York, NY 10036.

20. Defendant Stifel, Nicolaus & Company ("Stifel") is a financial services company with principal executive office located at 501 N. Broadway, St. Louis, MO 63102.

21. Defendant William Blair & Company, L.L.C. ("William Blair") is a financial services company with principal executive office located at 666 Fifth Avenue, New York, NY 10103.

22. Defendant Janney Montgomery Scott LLC ("Janney") is a financial services company with principal executive office located at 1717 Arch Street, Philadelphia, PA 19103.

23. Defendants Morrison, Kalowski, Harrison, Barberich, Kessler and Yanchik are referred to herein as the "Individual Defendants."

24. Defendants BMO, Stifel, William Blair and Janney (the "Underwriter Defendants") are named as defendants herein for the claims arising under the Securities Act. They were the underwriters of the IPO, assisting in the drafting and dissemination of the offering documents and the sale of the Company's IPO shares to the investing public.

SUBSTANTIVE ALLEGATIONS

25. The First Circuit has described the three phases of clinical trials of a candidate drug for FDA approval:

> - Phase 1 clinical trials, generally conducted on 20 to 80 healthy volunteers to determine how the drug works in humans;
> - Phase 2 clinical trials, generally involve no more than several hundred subjects and are designed to evaluate the effectiveness of the drug, as well as short-term side-effect; and
> - Phase 3 clinical trials, generally involve several hundred to several thousand subjects and are designed to gather information necessary to provide a basis to label the drug.
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> *See N.J. Carpenters Pens. & Ann. Fund v. Biogen Idec, Inc.,* 537 F.3d 35, *39 (2008).

26. As set forth herein, the Phase 2 and 3 clinical trials of galeterone severely digressed from the standards for clinical trials set forth in regulations administered by the FDA, as observed by the First Circuit.

27. The Registration Statement stated that galeterone is "a highly selective, multi-targeted, oral small molecule drug candidate that we believe has advantages over existing prostate cancer therapies." However, as stated in the Registration Statement, galeterone was still a "drug candidate" because it had not completed the clinical trials necessary for FDA approval, without which the drug cannot be sold.

28. The Registration Statement also stated that galeterone may reduce the risk of or delay the development of resistance to therapy and provide efficacy in patients with tumors resistant to other treatments; and that "data from the subset of patients in our ARMOR2 trial and data from preclinical studies conducted by us and independent laboratories [indicate that] galeterone may have the ability to treat both patients with full-length androgen receptors and patients with C-terminal loss, including AR-V7."

29. The Registration Statement also said that going forward, Tokai would:

> Complete the clinical development of and seek marketing approval for galeterone for the treatment of CRPC patients with prostate cancer tumors that express the AR-V7 splice variant. Based on discussions with the FDA, we expect that our ARMOR3-SV trial will be a randomized, open label clinical trial comparing galeterone to Xtandi in up to 170 metastatic CRPC treatment-naive patients whose prostate tumors express the AR-V7 splice variant. We expect to commence the trial in the first half of 2015 and, subject to patient enrollment rates and the rates of disease progression in patients in the trial, to have top-line data from the trial by the end of 2016.

30. The Registration Statement was materially false and misleading for the reasons set forth herein.

31. Galeterone targets a very specific subpopulation of prostate cancer patients who are treated specifically for CRPC *and* have the AR-V7 genetic trait. Prior to Tokai's IPO, two drugs competed for the CRPC market: Zytiga (approved in 2011) and Xtandi (approved in 2012). However, both drugs failed to show results in a sub-subpopulation of CRPC patients with the truncated androgen receptor, known as AR-V7. Galeterone which targeted the AR-V7 variant had no reasonable chance of being approved by the FDA.

32. First, prior to the filing and dissemination of the Registration Statement, Tokai never conducted a Phase 2 trial designed to test the effectiveness of galeterone on AR-V7 patients. Nor did it run a comparative trial designed to test the drug's effectiveness against Zytiga and Xtandi. Instead, the Company merely ran a Phase 2 trial testing galeterone for effectiveness in CRPC prostate cancer, evaluating 87 cancer patients classified as CRPC. The data included 17 patients who were non-metastatic and treatment naive (no other drugs given) and 38 patients who were metastatic and treatment naive. It also included 26 patients who had received Zytiga and five who had received Xtandi.

33. Lacking any reasonable basis to contend that galeterone is more effective, if at all, than either Zytiga and Xtandi, and aware that an article entitled "AR-V7 And Resistance To Enzalutamide And Abiraterone In Prostate Cancer," (the "NEJM Article") being prepared for publication in the New England Journal of Medicine would state that Zytiga and Xtandi were not effective in AR-V7 patients, the defendants conducted an after-the-fact analysis of Tokai's Phase 2 trial and did a so-called "retrospective subset analysis," which is actually *post hoc* rationalization, to be able to represent in the Registration Statement that Tokai's focus was on AR-V7; that six out of the 87 patients in the study had AR-V7; and that galeterone appeared to have some efficacy in five of those patients.

34. The NEJM Article was published in the New England Journal of Medicine on September 3, 2014 at NEJM.org. Tokai was aware of the upcoming publication of the NEJM Article because one of its authors - Dr. Mario Eisenberger - was also a lead contributor on the galeterone Phase 2 trial.

35. The material change of Tokai's business model is evident from a review of the Company's preliminary and final registration statements, each iteration placing greater and more frequent emphasis on AR-V7. Moreover, while the final Registration Statement said that galeterone appeared to have some efficacy in six of seven AR-V7 patients, an earlier draft represented that "four patients were identified as having altered androgen receptors that were truncated, all of whom showed clinically meaningful PSA reductions of at least 50%."

36. Accordingly, Tokai's business model, prospects and clinical trial results were materially revised shortly before the filing of the Registration Statement, in order to differentiate galeterone from existing products and induce investors to purchase Tokai shares. The Registration Statement failed to disclose that Tokai never conducted a Phase 2 trial designed to test the effectiveness of galeterone on AR-V7 patients; that the Company had materially changed its focus shortly before the IPO; that the six AR-V7 patients who showed improvement had very recently been only four; and that its so-called "test results" were actually predicated on a to-be-published NEJM Article. These facts were material to investors because they would have reasonably concluded that the Company was going public with no viable business plan.

37. Second, Tokai's design of galeterone's Phase 3 trial was flawed and virtually guaranteed to fail. Tokai was embarking on its Phase 3 trial blind, as no prior testing had

been done to measure the drug's effectiveness in AR-V7 patients, and the very structure of its Phase 3 test was woefully inadequate.

38. As an initial matter, the FDA typically requires the successful completion of two well-controlled clinical trials involving 300 to 3,000 volunteers, to support approval. In the case of galeterone, however, Tokai planned only a *single* trial involving merely 170 patients. (For comparative purposes, the Phase 3 study size for Xtandi involved 1,199 patients; the study for Zytiga involved 1,195 patients).

39. To make matters worse, galetrone's Phase 3 trial was unprecedented. Tokai abandoned its Phase 2 trial design and formulated an entirely new trial design with two principal characteristics: (i) whereas the Phase 2 trial was evaluating galeterone as a stand-alone drug, Tokai designed its Phase 3 trial to compare galeterone specifically to Xtandi; and, (ii) whereas the Phase 2 trial used a decreased PSA level as an endpoint, Tokai changed its endpoint to be radiographic progression free survival ("PFS"), which the FDA noted was itself inadequate. Thus, not only did Tokai change the very subject of the test, but also how success would be measured.

40. Finally, the FDA had not approved a diagnostic test for identifying patients with AR-V7 and, in the absence of such FDA approval, a drug targeted at AR-V7 could not be sold. Thus, Tokai was proposing to use a non-approved test for its Phase 3 trial to identify AR-V7 patients, notwithstanding the fact that the FDA would not authorize the commercial sale of galeterone based on a diagnostic which had not received its prior approval.

41. Tokai had no idea what outcome to expect from the Phase 3 trial since the test group and endpoint were so changed that it was as if no Phase 2 trial had ever occurred. Nor

would any test result be useful, since no FDA-approved test existed, or was pending approval, for identifying patients with AR-V7.

42. Plaintiff relied on the statements in the Registration Statement for the September 17, 2014 IPO. Based on this reliance, he purchased 200,000 shares of Tokai on the open market between January 1 and April 16, 2015 for an aggregate amount of $2,596,781.67.

43. Tokai publicly announced commencement of the Phase 3 trials in June 2015. On June 24, 2015, Tokai issued a press release entitled "Tokai Pharmaceuticals Announces Initiation of Phase 3 ARMOR3-SV Trial of Galeterone in AR-V7 Positive Metastatic Castration-Resistant Prostate Cancer." The press release stated, in part:

> ARMOR3-SV represents an important step forward in bringing precision medicine to patients with prostate cancer, and we are pleased with the progress made by our valued collaborator Qiagen in readying the AR-V7 clinical assay for global implementation," said Jodie Morrison, President and Chief Executive Officer of Tokai. "With worldwide commercial rights to galeterone, our pivotal clinical trial on track to read out by the end of 2016, and a strong financial position, Tokai is well positioned to realize its mission of bringing new therapeutic treatment options to patients with prostate cancer.
>
> . . .
>
> Based on the evidence reported thus far, a diagnostic tool that can predict patient responsiveness to certain therapies should lead to more informed treatment decisions and ultimately better care for prostate cancer patients," said Mary Ellen Taplin, M.D., Director of Clinical Research, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute and lead U.S. investigator of ARMOR3- SV. "Given the encouraging clinical data reported to date for galeterone and the precision medicine approach being employed in Tokai's pivotal trial, this study has the opportunity to alter the treatment landscape for metastatic CPRC patients."
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> . . .
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> The company expects topline data from ARMOR3-SV to be available by the end of 2016.

44. Tokai's first public misstatement about the number of test subjects occurred in August 2015, less than three months after announcement of the Phase 3 trials. On August 12, 2015, Tokai filed a Quarterly Report on Form 10-Q with the SEC, stating in part:

> We have initiated our pivotal Phase 3 clinical trial of galeterone, which we refer to as ARMOR3-Splice Variant, or ARMOR3-SV, in metastatic CRPC patients whose tumor cells express AR-V7. In ARMOR3-SV, ***we are comparing galeterone to Xtandi® (enzalutamide) in 148 metastatic CRPC patients*** who have not received other second-generation oral therapies or chemotherapy for their CRPC. The primary endpoint of ARMOR3-SV is radiographic progression-free survival assessed by blinded independent central review. Selection of patients with AR-V7 is made using a clinical trial assay optimized for global use by our collaborator, Qiagen. Implementation of the clinical trial assay is ongoing and screening of eligible patients is expected to begin this quarter. The design of ARMOR3-SV is informed by feedback that we obtained from the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency. We expect top-line data from ARMOR3-SV to be available by the end of 2016. We have been given fast track designation by the FDA for galeterone for the treatment of CRPC.

45. On August 12, 2015, Tokai also issued a press release entitled "Tokai Pharmaceuticals Reports Second Quarter 2015 Results." The press release stated, in part:

> Tokai's business highlights for the quarter include the initiation of ARMOR3-SV, Tokai's pivotal Phase 3 clinical trial of galeterone in men with metastatic castration-resistant prostate cancer (mCRPC) whose tumor cells express the AR- V7 splice variant, which is a truncated form of the androgen receptor that has been associated with non-responsiveness to commonly-used oral therapies for mCRPC.
>
> ARMOR3-SV is designed to evaluate whether administration of galeterone results in a statistically significant increase in radiographic progression free survival as compared to Xtandi® (enzalutamide) ***in 148 treatment-naive mCRPC patients whose prostate tumor cells express the AR-V7 splice variant.*** This trial represents the first pivotal trial in prostate cancer that employs a precision medicine approach for patient selection. The design and clinical rationale for ARMOR3- SV was presented last quarter at the 2015 Annual Meeting of the American Society for Clinical Oncology. Topline data from ARMOR3-SV are anticipated by the end of 2016.
>
> . . .

> "We believe that AR-V7 positive metastatic CRPC represents a significant unmet market opportunity, and that ARMOR3-SV has the potential to change the treatment landscape for metastatic CRPC patients by enabling treating physicians to make more informed treatment decisions," said Jodie Morrison, President and Chief Executive Officer of Tokai. "We are pleased with our progress in initiating ARMOR3-SV globally, and with screening of patients beginning this quarter, we expect topline data from the study by the end of next year. ***With worldwide rights to galeterone and a pipeline of candidates from our ARDA discovery platform, a strong financial position and pivotal data expected next year, we are well positioned to create value from Tokai's pipeline*** and achieve our mission of developing and delivering innovative therapies that provide hope and healing for patients living with cancer."

(Emphasis added.)

46. Again, Plaintiff in reliance on these and other statements by the Defendants purchased an additional 800,000 shares of Tokai in open market transactions between August 28 and November 3, 2015 in the aggregate amount of $9,386,614.89.

47. Tokai continued misrepresenting the number of test subjects. On November 10, 2015, Tokai filed a Quarterly Report on Form 10-Q with the SEC, stating, in part:

> We are conducting a pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in ***approximately 148 CRPC patients*** whose prostate tumors express the AR-V7 splice variant.

(Enphases added.)

48. On March 10, 2016, Tokai filed an Annual Report on Form 10-K with the SEC, announcing the Company's financial and operating results for the quarter and year ended December 31, 2015 (the "2015 10-K"). In the 2015 10-K, Tokai stated, in part:

> We are conducting a pivotal Phase 3 clinical trial comparing galeterone to Xtandi® (enzalutamide) in ***approximately 148 treatment-naive mCRPC patients*** whose prostate tumors express the AR-V7 splice variant.

(Emphasis added.)

49. The foregoing post-Registration Statement statements were materially false and/or misleading and failed to disclose that: (i) there were significant structural and other problems with the Company's ARMOR3-SV study trial design; (ii) Tokai was not able to recruit anything close to 148 viable test subjects, as when the study ended, there were only 38 test subjects in total and only four who met the requirements for the study; (iii) consequently, ARMOR3-SV was unlikely to succeed in meeting its primary endpoint; (iv) as a result, commercialization of galeterone was less likely and/or imminent than Tokai had led investors to believe; and (v) as a result of the foregoing, the representations concerning Tokai's business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis.

50. Given the significantly flawed, inadequate, and insufficient testing, galeterone had no reasonable chance of success. On July 26, 2016, only two and one-half months after assuring investors that Tokai had made "significant progress in our clinical development program for galetrone," that it had "continued to accelerate screening and enrollment," that it had "strengthened" its development team, and that it looks forward to "continued progress in the months ahead," the Company announced the discontinuance of the Phase 3 trial following the recommendation made by the trial's independent Data Monitoring Committee on July 25, 2016. According to the Company:

> [T]he DMC determined that the ARMOR3-SV trial will likely not succeed in meeting its primary endpoint of demonstrating an improvement in radiographic progression-free survival ("rPFS") for galeterone versus enzalutamide in AR-V7 positive mCRPC.
>
> The Company essentially admitted that continuing the Phase 3 trial was futile.

51. Shortly after the discontinuance of the Phase 3 trial, Tokai announced in a Form l0-Q a reduction of approximately 60% of its workforce and stated that "there is a

substantial likelihood that the Company will not pursue the development of galeterone in AR-V7 positive CRPC in the future."

52. The Company's July 26, 2016, announcement caused the price of Tokai common stock to fall precipitously. The stock fell from a closing price of $5.20 on July 25, 2016, to a closing price of $1.10 on July 26, 2016, after Tokai publicly announced discontinuance of its Phase 3 trial.

53. Plaintiff sold his all of his holdings of Tokai after the Company's July 26, 2016 announcement at prices between $1.2027 and $1.0576 per share, a loss of well over 90%.

54. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff has suffered damages in excess of $10 million.

LOSS CAUSATION

55. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff.

56. Plaintiff purchased Tokai's securities at artificially inflated prices and was damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS (WITH RESPECT TO THE EXCHANGE ACT CLAIMS)

57. As alleged herein, Tokai and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name

of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the Exchange Act. As set forth elsewhere herein in detail, these Defendants, by virtue of their receipt of information reflecting the true facts regarding Tokai, his/her control over, and/or receipt and/or modification of Tokai's materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Tokai, participated in the fraudulent scheme alleged herein.

58. The critical role that the success of galeterone's clinical trials played in Tokai's continued operations provides cogent evidence of fraudulent intent or recklessness. During the relevant time-period, Tokai never generated *any* revenue from *any* product sales and had incurred significant losses since its inception. Galeterone was only product for which Tokai was seeking FDA approval. In fact, Tokai's Registration Statement admitted that ***"[i]f clinical trials of galeterone and our future product candidates, including our ongoing Phase 2 clinical trial and our planned pivotal clinical trial of galeterone, fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or are not otherwise successful, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of galeterone and our future product candidates.*** Registration Statement at 15 (emphasis in original).

59. The centrality of galeterone's successful clinical trials to Tokai's going concern created undue pressure for the Company, its management and its investment

bankers to make positive statements about the progress of clinical trials and to omit to disclose negative information. The nascent development of Tokai and its having only one drug candidate in line for FDA approval provides compelling evidence that misstatements and omissions were not made in error.

60. With respect to the Registration Statement, several of the misstatements and omissions are so glaring that they provide compelling evidence of scienter. Although the Registration Statement provides that galeterone "has advantages over existing prostrate cancer therapies," Tokai never conducted a Phase 2 test designed to test the effectiveness of the drug candidate on AR-V7 patients, let alone in comparison to Zytiga and Xtandi. Furthermore, Tokai did not disclose that its test results were based on an imminent article in the NEJM, or that its clinical design was faulty.

61. With respect to the public statements made after announcement of the Phase 3 clinical trials, again, glaring errors provide evidence of scienter. For a Phase 3 clinical trial to have only four viable subjects at the same time when Tokai disclosed 148 simply could not have been a mistake. Significantly, such disclosure was never made by the Company, but during meeting of clinical oncologists in 2017. The Defendants cannot argue that they did not have access to the number of test subjects at the time that they made fraudulent public statements. Furthermore, Tokai did not disclose critical design flaws in the Phase 3 trial that were so severe that the FDA could not have given approval to galeterone. An omission of such starkness counters any inference of non-fraudulent intent.

APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE) (WITH RESPECT TO THE EXCHANGE ACT CLAIMS)

62. The market for Tokai's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Tokai's securities traded at artificially inflated prices during the relevant period. Plaintiff purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Tokai's securities and market information relating to Tokai, and have been damaged thereby.

63. The artificial inflation of Tokai's stock was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff. As described herein, Tokai and the Individual Defendants made or caused to be made a series of materially false and/or misleading statements about Tokai's clinical trials, business, operations, and prospects. These material misstatements and/or omissions created an unrealistically positive assessment of Tokai and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company stock. These Defendants' materially false and/or misleading statements resulted in Plaintiff purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

64. At all relevant times, the market for Tokai's securities was an efficient market for the following reasons, among others:

(a) Tokai stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Tokai filed periodic public reports with the SEC and/or the NASDAQ;

(c) Tokai regularly communicated with public investors *via* established market communication mechanisms, including

through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Tokai was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

65. As a result of the foregoing, the market for Tokai's securities promptly digested current information regarding Tokai from all publicly available sources and reflected such information in Tokai's stock price. Under these circumstances, Plaintiff suffered injury through his purchase of Tokai's securities at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

66. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false or misleading statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent that certain of the statements alleged to be false or misleading may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Tokai and the Individual Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements

was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Tokai who knew that the statement was false when made.

COUNT I

For Violations of Section 11 of the Securities Act of 1933 (Against All Defendants)

67. Plaintiff repeats and re-alleges the allegations of paragraphs 1 though 66 above as if fully set forth herein.

68. This Cause of Action is brought pursuant to § 11 of the Securities Act, 15 U.S.C. § 77k, against all Defendants. This claim does not sound in fraud. For purposes of this Section 11 claim, Plaintiff does not allege that any Defendant acted with scienter or fraudulent intent, which are not elements of a claim under Section 11 of the Securities Act of 1933. This claim is based solely on strict liability as to Tokai, and negligence as to the remaining Defendants. Plaintiff specifically disclaims any allegation of fraud, scienter or recklessness in this Section 11 claim.

69. The Registration Statement was materially false and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein. Defendant Tokai is strictly liable to Plaintiff for the misstatements and omissions. None of the other Defendants named herein made a reasonable investigation or possessed reasonable grounds or the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

70. By reason of the conduct herein alleged, each Defendant named herein violated, and/ or controlled a person who violated, Section 11 of the Securities Act.

71. Plaintiff acquired Tokai common stock traceable to the IPO. Because this was Tokai's first and only IPO, all shares purchased by Plaintiff are traceable to the IPO. According to the Registration Statement at 146, "[p]rior to this offering, there has been no public market for our common stock. . . ."

72. Plaintiff has sustained damages. The value of Tokai common stock has declined substantially subsequent to and due to these Defendants' violations.

73. At the time of Plaintiff's purchases of Tokai common stock, Plaintiff was without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to the disclosures herein. Less than one year has elapsed from the time that Plaintiff discovered or reasonably could have discovered the facts upon which this complaint is based to the time that Plaintiff commenced this action. Less than three years have elapsed between the time that the securities upon which this Count is brought were offered to the public and the time Plaintiff commenced this action.

COUNT II

For Violations of Section 12(a)(2) of the Securities Act of 1933 (Against All Defendants)

74. Plaintiff repeats and re-alleges the allegations of paragraphs 1 though 66 above as if fully set forth herein.

75. This claim is asserted against Tokai, the Individual Defendants, and the Underwriter Defendants. This claim does not sound in fraud. For purposes of this Section 12(a)(2) claim, Plaintiff does not allege that any Defendant acted with scienter or fraudulent

intent, which are not elements of a claim under Section 12(a)(2) of the Securities Act of 1933. This claim is based solely on negligence. Plaintiff specifically disclaims any allegation of fraud, scienter or recklessness in this Section 12(a)(2) claim.

76. By means of the defective Registration Statement, Tokai, the Individual Defendants and the Underwriter Defendants promoted and sold Tokai stock to Plaintiff.

77. The Registration Statement contained untrue statements of material fact, and/ or concealed or failed to disclose material facts, as detailed above. The Defendants owed Plaintiff who purchased Tokai common stock pursuant to the Registration Statement the duty to make a reasonable and diligent investigation of the statements contained therein to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to make the statements contained therein not misleading. These Defendants, in the exercise of reasonable care, should have known of the misstatements and omissions contained in the Registration Statement as set forth above.

78. Plaintiff did not know, nor in the exercise of reasonable diligence could have known, of the untruths and omissions contained in the Registration Statement at the time Plaintiff acquired Tokai common stock.

79. Plaintiff acquired Tokai common stock traceable to the IPO. Because this was Tokai's first and only IPO, all shares purchased by Plaintiff are traceable to the IPO. According to the Registration Statement at 146, "[p]rior to this offering, there has been no public market for our common stock. . . ."

80. By reason of the conduct alleged herein, Defendants violated section 12(a)(2) of the Securities Act. As a direct and proximate result of such violations, Plaintiff purchased

Tokai common stock pursuant to the Registration Statement sustained substantial damages in connection with their purchases of the stock.

81. Plaintiff, who has sold his common stock, seek damages to the extent permitted by law.

COUNT III

For Violations of Section 15 of the Securities Act of 1933 (Against the Individual Defendants)

82. Plaintiff repeats and re-alleges the allegations of paragraphs 1 though 66 above as if fully set forth herein.

83. This claim is asserted against the Individual Defendants.

84. This claim does not sound in fraud. For the purposes of this Section 15 claim, Plaintiff does not allege that any Defendant acted with scienter or fraudulent intent, which are not elements of a claim under Section 15 of the Securities Act of 1933. This claim is based solely on negligence. Plaintiff specifically disclaims any allegation of fraud, scienter or recklessness in this Section 15 claim.

85. The Individual Defendants each were control persons of Tokai by virtue of their positions as directors and/or senior officers of Tokai.

86. The Individual Defendants each were culpable participants in the violations of Section 11 of the Securities Act alleged in Count One above, based on their having signed or authorized the signing of the Registration Statement and having otherwise participated in the process which allowed the IPO to be successfully completed.

COUNT IV

For Violation of Section 10(b) of The Exchange Act and Rule l0b-5 Promulgated Thereunder Against All Defendants

87. Plaintiff repeats and re-alleges the allegations of paragraphs 1 though 66 above as if fully set forth herein.

88. Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the relevant time period, did: (i) deceive the investing public, including Plaintiff, as alleged herein; and (ii) cause Plaintiff to purchase Tokai's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

89. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Tokai's securities in violation of Section 10(b) of the Exchange Act and Rule l0b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

90. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Tokai's financial well-being and prospects, as specified herein.

91. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Tokai's value and performance and continued substantial growth, which included the making of, or the

participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Tokai and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities.

92. Each of the Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the relevant time period and members of the Company's management team or had control thereof; (ii) each of these Defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these Defendants enjoyed significant personal contact and familiarity with the other Defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances and operations at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

93. The Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done

knowingly or recklessly and for the purpose and effect of concealing Tokai's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

94. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Tokai's securities was artificially inflated during the relevant period of time. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants, Plaintiff acquired Tokai's securities at artificially high prices and were damaged thereby.

95. At the time of said misrepresentations and/or omissions, Plaintiff was ignorant of their falsity, and believed them to be true. Had Plaintiff and the marketplace known the truth regarding the problems that Tokai was experiencing, which were not disclosed by Defendants, Plaintiff would not have purchased or otherwise acquired their Tokai securities, or, if he had acquired such securities, he would not have done so at the artificially inflated prices which he paid.

96. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

97. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered damages in connection with his respective purchases and sales of the Company's securities.

COUNT V

For Violation of Section 20(a) of The Exchange Act Against the Individual Defendants

98. Plaintiff repeats and re-alleges the allegations of paragraphs 1 though 66 above as if fully set forth herein.

99. The Individual Defendants acted as controlling persons of Tokai within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

100. In particular, each of these Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to

have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

101. As set forth above, Tokai and the Individual Defendants each violated Section 10(b) and Rule l0b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered damages in connection with their purchases of the Company's securities.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Awarding compensatory damages in favor of Plaintiff and against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, but not less than $10,835,724, including interest thereon;

B. Awarding Plaintiff his reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

C. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Pursuant to Fed. R. Civ. P. 38, Plaintiff hereby demands a trial by jury of all issues triable by jury.

Dated: July 25, 2017

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